Endovascular Treatment of Aorta-Iliac Aneurysms with a Flared Iliac Limb

Stevo Duvnjak, MD, PhD, EBIR[1,2] Tomas Balezantis, MD[3]

[1] Department of Radiology, Odense University Hospital, Odense C, Denmark
[2] Department of Clinical Research, University of Southern Denmark, Denmark
[3] Department of Thoracic, Vascular and Cardiac Surgery, Odense University Hospital, Odense C, Denmark

Address for correspondence Stevo Duvnjak, MD, PhD, EBIR, Department of Radiology Odense University Hospital, Sdr. Boulevard 29. Odense 5000 C, Denmark (e-mail: duvnjak.stevo@gmail.com).

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Abstract

Endovascular abdominal aneurysm repair (EVAR) relies on the quality of the proximal and distal landing zone. Reinterventions are higher in patients with suboptimal landing zone. The study aimed to evaluate reintervention rate after endovascular treatment of an aorta-iliac aneurysm using the flared iliac limbs.

The retrospective study included 179 patients treated with EVAR at a single university hospital institution from January 2011 to January 2014 of which 75 patients (42%) were treated with flared iliac limb stent graft and 104 patients (58%) were treated with a nonflared iliac limb stent graft. There were 165 male patients (92%), mean age was 75.8 $\pm$ 6.6 years.

Thirty-six patients underwent secondary treatment accounting for overall reintervention rate of 20%. Endoleak type 1b occurred in 13 patients (7%), followed by endoleak type 1a in six patients (3%). Endoleak type 2 occurred in seven patients (4%) requiring the treatment due to abdominal aortic aneurysm (AAA) enlargement, endoleak type 3 in three patients (2%), and leg stent graft thrombosis in seven patients (4%). In 143 patients (80%), there were no secondary interventions during the follow-up period. Reintervention due to endoleak type 1b was statistically significantly higher in a flared iliac limb group ($p < 0.02$) with the rate of 7.2% compared with 1.9% rate in nonflared iliac limb group. The mean follow-up was 44.3 $\pm$ 20.4. Overall mortality was 33%. Flared iliac limb with a distal diameter of $\geq$ 20 mm, show a higher rate of iliac limb reintervention in a follow-up period due to endoleak type 1b.

Keywords

- endoleak
- abdominal aortic aneurysm
- endovascular abdominal aneurysm repair
- common iliac artery

Endovascular abdominal aneurysm repair (EVAR) is a well-established treatment for abdominal aortic aneurysm (AAA); it has lower short-term morbidity and mortality rates in comparison to open surgery but increasing rates of reintervention.[1–3] In 20 to 40% of patients with AAA, a concomitant common iliac artery (CIA) an aneurysm or dilatation may be present, while the occurrence of an isolated CIA is limited.[4]

The quality of the CIA presents the distal landing zone for EVAR and in the case of an artery aneurysm and/or dilatation, the seal could be compromised.[5] There are a variety of endovascular techniques available to treat an aorta-iliac aneurysm such as the occlusion of the internal iliac artery and the extension of the landing zone to the external iliac artery with known pelvic ischemic complications, or a flared iliac limb with a maximal diameter of 28 mm. Furthermore, the branched iliac stent graft, the snorkel and sandwich techniques, and the hybrid intervention technique can also be used in those patients.[6,7] Compared with other techniques which preserve the internal iliac artery, the flared iliac limb presents the simplest intervention and has a shorter operation time.[8,9] However, the reintervention and occurrence of type Ib endoleak when using this technique is a major

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concern mainly due to the risk of continued CIA dilatation.[10] Aneurysmal or dilated CIAs expand twice as much compared with the growth rate of nonaneurysmal CIAs.[11]

This study primarily aimed to evaluate reintervention rates due to type Ib endoleak after the endovascular treatment of an aorta-iliac aneurysm using the flared iliac limb. The secondary aim of this study was the overall analysis of reintervention and survival of the entire patient cohort.

Materials and Methods

Study Design

This study was a single-center retrospective analysis of consecutively treated patients at a university hospital institution from January 2011 to January 2014. Patients were identified from vascular and radiological records. Any patients treated for isolated iliac limb due to isolated iliac artery aneurysm or patients treated with EVAR after a previous aortic surgery complicated with anastomotic pseudoaneurysm and/or a mycotic aneurysm were excluded from this study. The patient with EVAR extended to the external iliac arteries or patient treated with branched iliac stent graft were excluded as well. Further, patients converted to open surgery at the same time as EVAR and patients with focal abdominal aortic dissection were also excluded from this study.

Study Population and Data Collection

The size indication for treatment of AAA was $\geq$ 5 cm in women or $\geq$ 5.5 cm in men; for CIA, the indication was an aneurysm $>$ 3.5 cm. The following data were analyzed: age, gender, the diameter of AAA or iliac artery aneurysm, type and a distal diameter of the stent graft, complications and reinterventions related to the EVAR, the maximal length of the follow-up period, and mortality. The presence of endoleak types 1 to 5 and eventual thrombosis and infection of the stent graft was defined as a complication related to the procedure. The reintervention technique included embolization, as well as aortic stent cuff placement, leg stent graft extension, thrombectomy, and femoral crossover bypass. Type II endoleaks, which caused AAA growth $\geq$ 5mm in the follow-up period, were treated. The cohort was divided into two groups, the first group treated with flared limb (defined as used iliac limb) with $\geq$ 20 mm in diameter and the nonflared iliac limb group where distal diameter was $<$ 20 mm.

EVAR

All patients had a preprocedural contrast-enhanced computed tomography (CT) of the abdomen and pelvis for evaluation of aneurysm anatomy and suitability for EVAR using the thin slice 1 mm for analysis. The endovascular procedure was performed under general anesthesia (and in some cases under local anesthesia) percutaneously or with surgical exposure of one or both femoral arteries. In all cases, the experienced physicians measured and assessed for the appropriate stent graft and then performed the intervention. Regarding the distal landing zone, the minimal accepted length was 15 mm. The cases with extensive calcifications, tortuosity, and mural thrombus were avoided. The intention was to use flared iliac limb with 10 to 20% oversizing. The maximal diameter of the CIA which was treated with flared limbs was up to 24 mm. The following stent grafts were used: Medtronic Endurant (Santa Rosa, CA) in 147 patients (82%), Zenith Cook (Cook Medical, Bloomington, IN) in 18 patients (10%), and GORE Excluder (W.L. Gore, Flagstaff, AZ) in 14 patients (8%).

Outcome Measure

The reintervention rate particularly due to type Ib endoleaks was compared between the groups; the reintervention, reasons for reintervention, and overall survival outcome were analyzed as well.

Follow-up

All patients had a clinical examination and CT after 3 months postoperative and were also scheduled for every following year.

Statistical Analysis

SPSS Statistics 23 (IBM SPSS Inc. Chicago, IL) software was used for analysis. Categorical data were expressed as the mean $\pm$ standard deviation (SD) or as median as appropriate. As appropriate, Student's t-test, χ^2, Fisher's exact, and two-tailed tests were all used to test significance. The survival analysis using the MedCalc software (Belgium) has been evaluated using the Kaplan–Meier model and $p < 0.05$ was considered statistically significant.

Ethics

Informed consent was obtained from all participants before the treatment. Approval from the local data protection agency was received with the journal number 17/7206. For this type of study, ethical committee approval was not necessary.

Results

Demographic and Procedural Results

In all, 194 patients were treated with EVAR from January 2011 to January 2014. Fifteen patients were excluded from the study due to nonadherence to the protocol. The detailed overview of reasons for exclusion is presented in ►**Fig. 1**. The study included 179 patients (358 iliac limbs) in which 125 iliac arteries (75 patients; 42%) were treated with a flared iliac limb stent graft and 233 iliac arteries (104 patients; 58%) were treated with a nonflared iliac limb stent graft. The mean diameter of the CIA in flared iliac limb group was 17.6 mm (range, 17–25 mm) and mean oversizing of the implanted leg was 18.2%. In the nonflared iliac limb group, the mean diameter of the CIA was 14 mm (range, 12–15 mm), and mean oversizing of the implanted leg was 16.2%. The minimum accepted length of the CIA for stent graft deployment was 15 mm in both groups, mean length was 34.7 mm (range, 15–57 mm). ►**Table 1** presents preoperative AAA characteristics and basic patient demographic data. There were 165 male patients (92%). There were a statistically significant higher number of female patients in the nonflared iliac limb group ($p < 0.02$). The mean age was 75.8 $\pm$ 6.6 years (range, 57–92 years). There was no statistical difference when comparing the

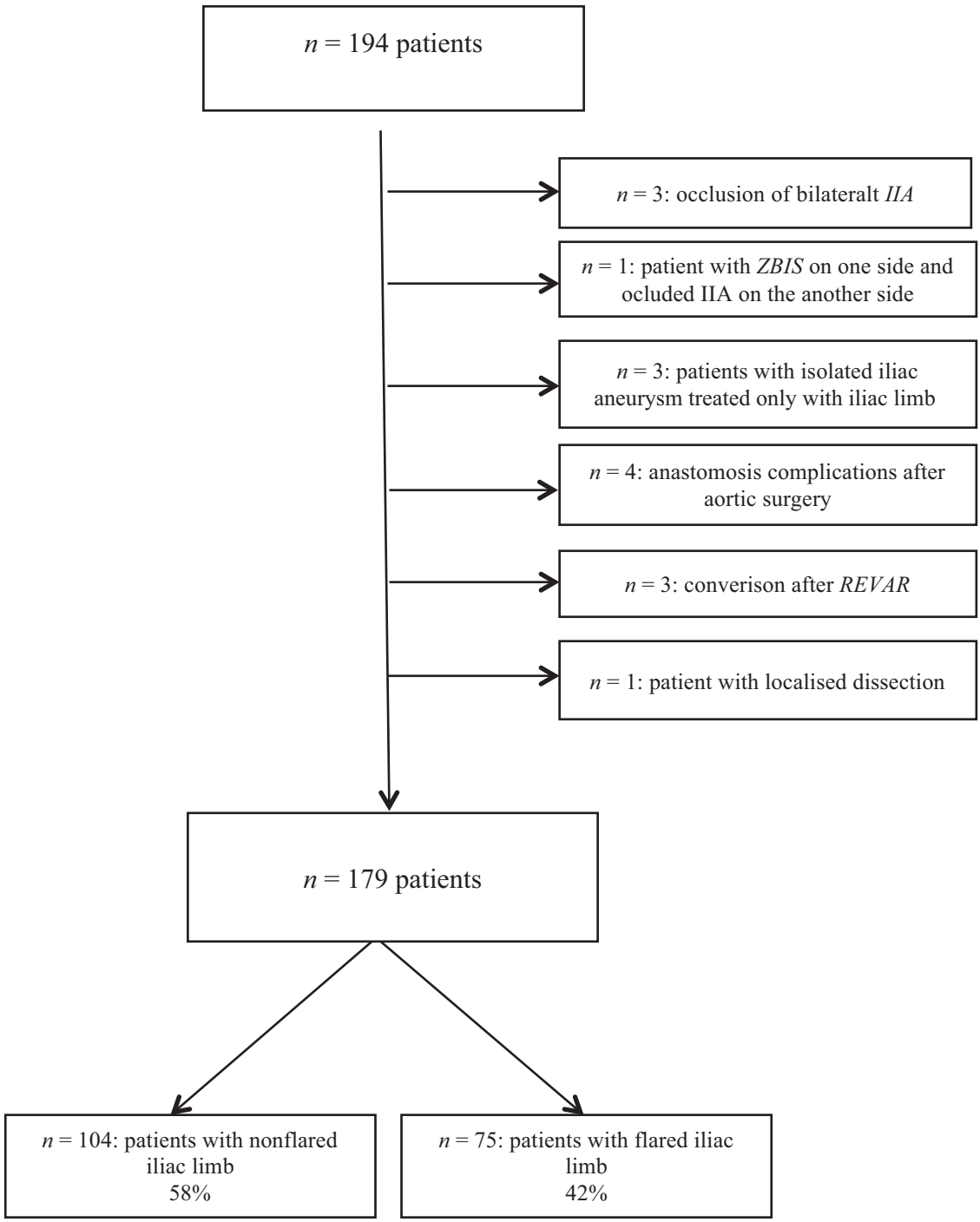

Fig. 1 Flow-chart with the number of included patients and overview of exclusion reasons IIA-internal iliac artery; *ZBIS*-branch iliac stent graft; *REVAR*-ruptured aneurysm treated with EVAR. EVAR, endovascular abdominal aneurysm repair.

age between the groups ($p = 0.18$). In the nonflared limb group, the mean age was 75.4 ± 6.6 years, and in the flared iliac limb group the mean age was 76.7 ± 6.3 years. There was no significant statistical difference in AAA diameter; in the flared iliac limb group, the mean AAA diameter was 62.8 ± 13.1 mm and in the nonflared iliac limb group, it was 63.8 ± 10.7 mm ($p = 0.61$). In 50 patients (67%) of the flared iliac limb group, a bilateral flared iliac limb was deployed, the unilateral flared iliac limb was deployed in 25 patients (33%).

Reintervention Rate

During the follow-up period, 36 patients underwent secondary treatment, accounting for an overall reintervention rate of 20%. In 13 patients (7%) type Ib endoleak occurred, followed by type Ia endoleak in six patients (3%). Type II endoleak occurred in seven patients (4%), requiring treatment due to AAA enlargement, while type III endoleak occurred in three patients (2%), and leg stent graft thrombosis in seven patients (4%). In 143 patients (80%), there were no reinterventions during the follow-up period. Reintervention rate due to endoleak type

Table 1 Patient demographic data and AAA characteristics

Variable	All ($n = 179$)	Flared iliac limb group $n = 75$ (42%)	Nonflared iliac limb group $n = 104$ (58%)	p-Value
Age (years)		76.7 ± 6.3	75.4 ± 6.6	$p = 0.18$
Male Female	$n = 165$ (92%) $n = 14$ (8%)	$n = 73$ (97%) $n = 2$ (3%)	$n = 92$ (88%) $n = 12$ (12%)	$p < 0.02$
AAA[a] diameter (mm)	64.3 mm (SD ± 12.5)	62.8 ± 13.1	63.8 ± 10.7	$p = 0.61$
REVAR[b]	$n = 24$ (13%)	$n = 9$ (12%)	$n = 15$ (14%)	$p = 0.64$

Abbreviation: AAA, abdominal aortic aneurysm.
[a]Abdominal aortic aneurysm.
[b]Ruptured abdominal aortic aneurysm treated with a stent graft.

Ib was statistically significantly higher ($p = 0.02$) in the flared iliac limb with the rate of 7.2% (97/125 limbs), comparing to the 1.9% (4/233) in the nonflared iliac limb group. Patients treated with flared iliac limbs had 4.2 times more risk to develop endoleak type 1b compared with the patients treated with limbs with < 20 mm in diameter. In patients with type Ib endoleak, additional limb extension was deployed with occlusion of the ipsilateral internal iliac artery in nine cases, and in four cases enough length was appreciated and leg extension was deployed in a CIAwithout occlusion of the internal iliac artery. In those four cases, the previously implanted limb had been placed proximally and distance to the iliac bifurcation was 25 to 30 mm. Therefore, it was possible to deploy limb extension without occlusion of the internal iliac artery. In all four cases, proximal migration of the previously deployed iliac limb was recorded. Spontaneous cessation of the endoleak occurred without additional intervention in three patients with type Ia endoleak, and aortic cuff and/or embolization of type Ia endoleak was performed with a successful outcome in three patients. All cases with type II endoleak were embolized successfully with coils and/or onyx. In two patients with type III endoleak, limb extension was deployed and one patient with type III endoleak died before reintervention due to a nonaneurysm related cause. In six patients with thrombosis, femoral–femoral crossover bypass was created (in one case, axillofemoral bypass) due to thrombosis of the aorta-uniiliac stent graft. There was no significant statistical difference regarding the overall reintervention rates between the groups; in the flared iliac limb group, 17 (23%) of 75 patients had reinterventions and reinterventions occurred in 19 (18%) of 104 patients in nonflared iliac limb group ($p = 0.47$). There were no cases with endoleak types IV and V or graft infection. The mean period to reintervention due to type Ib endoleak was 24.7 ± 17.0 months in the flared iliac limb group and 22.4 ± 17.9 months in the nonflared iliac limb group, without significant difference between the groups ($p = 0.32$). Two patients who experienced endoleak displayed symptoms and received unscheduled examinations. In the first patient with type Ib endoleak, a rupture occurred 46 months after successful EVAR treatment with leg extension (►**Fig. 2A–D**). In the second patient, the type II endoleak was first treated with embolization 14 months after the EVAR; a type Ia endoleak occurred 20 months later and was treated emergently with an aortic cuff but the patient died. In all other cases, endoleak was asymptomatic and discovered on routine surveillance.

Survival Analysis

The mean follow-up for the entire cohort was 44.3 ± 20.4 months (range, 3–81 months). Overall mortality was 33% during the follow-up period. In the flared iliac limb group, mortality was 35% (26 of 75 patients), and in the nonflared iliac limb group, the mortality rate was 32% (32 of 104 patients) without significant difference ($p = 0.42$), presented in ►**Fig. 3**. The mean follow-up period in patients with type Ib endoleak was 38.6 ± 23.3 months (range, 2–74 months) in the flared iliac limb group, and in the non-flared iliac limb group, the mean follow-up was 30.8 ± 19.4 months (range, 2–81 months) with no significant difference ($p = 0.96$). There was one case with late rupture of the AAA due to a type Ia endoleak 34 months after EVAR; in all other cases, mortality was not aneurysm-related.

Discussion

The main result in this retrospective study was that reintervention due to type Ib endoleak was significantly higher in patients treated with flared iliac limbs compared with those treated with nonflared iliac limbs.

When a stent graft is placed in an already dilated iliac artery, faster progression of vessel degeneration may occur in the future. Ballotta et al,[11] Richards et al,[12] and Falkensammer et al[13] report the faster growth of dilated CIA compared with non-dilated CIA. EVAR with flared iliac limb technique will result in initially favorable outcomes with a low rate of complication, as in the present study; however, over time the aneurysm will progress, and the result could be the occurrence of the endoleak. McDonnell et al[10] describe the higher rate of type Ib endoleak 7% after a mean follow-up of 30 months when flared iliac limb was used. Gray et al[14] recently published similar results of a 7.5% incidence with type Ib endoleak. These results also indicated that the limb graft with a diameter of ≥ 20 mm had a significantly higher rate of late-type Ib endoleak incidence compared with the limb graft with a diameter of < 20 mm.

Further, Hobo et al[15] show a large series cumulative incidence of type Ib endoleak in 9.1% of patients with dilated

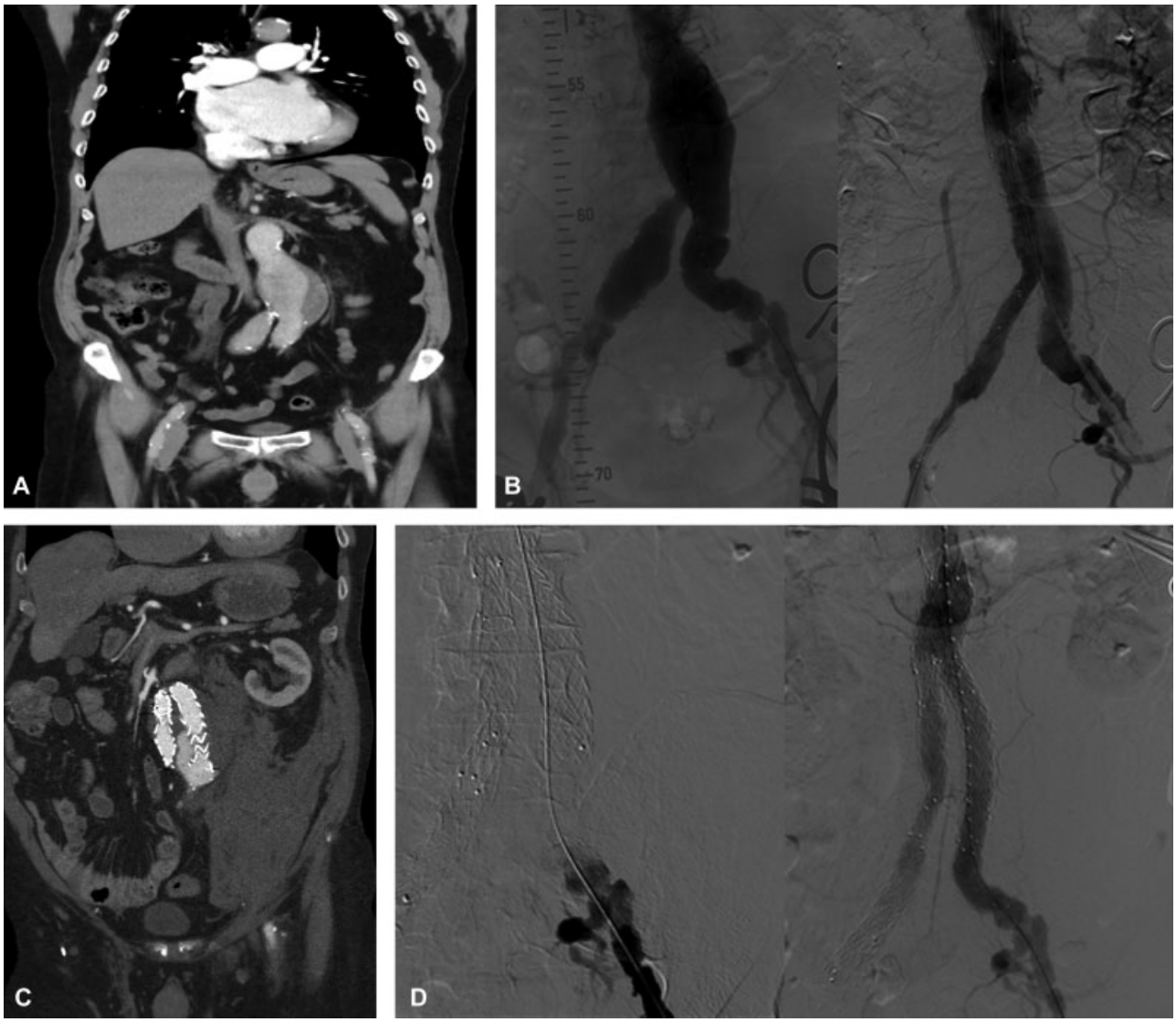

Fig. 2 (**A**) A 75-year-old male patient with 56 mm AAA and aneurysm of the right iliac artery with the diameter of 26 mm. The left common iliac artery has the diameter of 20 mm. (**B**) Intraoperative angiographic detail before and after stent graft deployment. The flared iliac limb with the diameter of 24 mm was deployed on the left side. On the right side, internal iliac was occluded, and a landing zone was in an external iliac artery. Control angiography after deployment showed no endoleak. (**C**) 46 months after EVAR the left leg is migrated proximally and AAA ruptured with the retroperitoneal hematoma on the left side. (**D**) Emergency percutaneous access on the left side. The angiographic images before and after deployment of the leg extension on the left side are presented in the figure. The leg extension 16 × 24 × 124 mm was deployed and control angiography showed good results and no endoleak. AAA, abdominal aortic aneurysm; EVAR, endovascular abdominal aneurysm repair.

CIA. In the present study, the rate of type Ib endoleak in the flared iliac limb group was 7.2%. One of the reasons for this could be that all our patients were controlled with CT which provides higher probability in discovering endoleak in an early phase before further enlargements of AAA occur. Further discrete migration of the iliac limb can be better appreciated on CT control, and reintervention is indicated to avoid the problem in the future.

The study from Torsello et al[16] reported a relatively low incidence of reintervention using the flared iliac limb technique on a patient with a compromised distal landing zone. The study included 89 patients who had a median follow-up time of 5 years. The reintervention rate was 8.4%, and the study concluded that complications and reinterventions were rare using this technique. Kirkwood et al[17] and Naughton et al[8] suggest that, based on their results, flared iliac limb is not accompanied by the statistically significant increased rate of type Ib endoleak. However, increased rate of type Ib endoleak is recorded. Further, Naughton et al[8] advocate for using the flared iliac limb if feasible due to a lower rate of complication and reintervention compared with the hypogastric exclusion and landing in the external iliac artery.

The other studies which include the bell-bottom technique report a higher rate of type Ib endoleak and reintervention,[18,19] suggesting that a longer follow-up period (usually after 3 years) is needed to observe the degeneration of an aneurysm at the distal stent graft location. Agu et al[20] reported a 2.4% incidence of developing iliac artery aneurysm in a 5 to 9 years of follow-up in 297 patients treated with EVAR with suitable distal landing zones, and they suggest

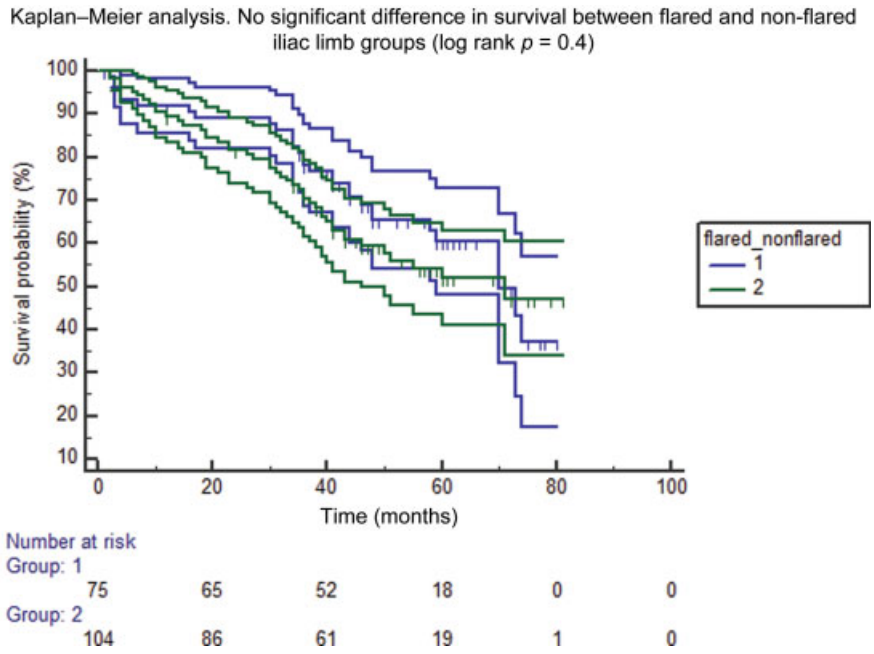

Fig. 3 Kaplan–Meier analysis. No significant difference in survival between flared and nonflared iliac limb groups (log rank; $p = 0.42$).

that a progressive degeneration of the iliac vessels occurs over time. The force applied on the flared iliac limb and the hemodynamic pattern is not the same as in a straight limb which can influence the outcome presented in an experimental study.[21] Limb graft oversizing can induce or accelerate iliac vessel degeneration as described in a report as well.[17]

Technical success and immediate results are good in the present study but the occurrence of the type Ib endoleak is to be expected in a mid- and long-term follow-up period. The higher nonaneurysm related mortality can justify the use of the flared iliac limb technique in some patient groups with a closer surveillance follow-up. The simplicity of the procedure and preserving the internal iliac artery in most patients are the main advantages of this technique. It is important to use the maximal length of the CIAas a landing zone and deploy the flared iliac limb close as possible to the iliac bifurcation to avoid limb proximal graft migration and endoleak.

Iliac branch graft technology allows us to treat more patients who have a compromised distal landing zone. The results of the iliac branch graft are good with fair patency rate and outcome.[5] There are some anatomical constraints and they should be respected during iliac branch graft deployment.[5,6]

The limitation of the present study is the retrospective design. Additionally, it is absent of precise analysis of the nonaneurysm related mortalities and in-depth analysis of iliac vessels; however, the cases with extensive calcification, tortuosity, and thrombus were not treated with EVAR. Further, inherent bias needs to be mentioned and different behavior of already degenerated iliac vessels in the flared iliac limbs prone to faster dilatation comparing to the normal diameter of iliac arteries in the nonflared group. The extent of aneurysmal changes in the common iliac artery, such as focal or diffuse enlargement of the artery, probably influenced behavior as well but the small number of the patient limited every conclusion in the present study.

Conclusion

In conclusion, flared iliac limb with a distal diameter of $\geq$ 20 mm shows a higher rate of iliac limb reintervention in a follow-up period due to type Ib endoleak. Flared iliac limb can be used, especially in an older subgroup of patients, with dilatation of the common iliac artery. However, before this technique is applied, it's very important to conduct a complete assessment and analysis of the distal landing zone, including the degree of calcifications and mural thrombus, the length of the distal zone, and tortuosity. Long-term surveillance is very important and usually, complications occur after a few years.

Conflict of Interest

Dr. S.D. reports personal fees from Medtronic and Boston Scientific.

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